

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

AVENTIS PHARMA S.A.,

Plaintiff,

v.

BAXTER HEALTHCARE CORP.,

Defendant.

BAXTER HEALTHCARE CORPORATION,

Counterclaimant,

v.

AVENTIS PHARMA S.A.,

Counterdefendant.

Civil Action No. 06-636-GMS

**JOINT STATUS REPORT**

Pursuant to the Court's Notice of Scheduling Conference dated June 13, 2007 and Fed. R. Civ. P. 16, Plaintiff Aventis Pharma S.A. ("Plaintiff") and Defendant Baxter Healthcare Corp. ("Defendant" or "Baxter"), hereby submit this Joint Status Report.

**I. PARTIES' MEET AND CONFER**

Pursuant to Rule 26(f), a meeting was held on June 20, 2007, by telephone, and was attended by: counsel for Plaintiff, Steven J. Balick of Ashby & Geddes and Paul W. Browning and Kakoli Caprihan of Finnegan, Henderson, Farabow, Garrett, & Dunner, LLP, and counsel for Defendant, Philip A. Rovner of Potter, Anderson & Corroon LLP and Julie J. Han and Eric A. Mercer of Townsend and Townsend and Crew LLP.



## **II. JURISDICTION AND SERVICE**

This is a patent case arising under the Patent Act, 35 U.S.C. § § 271 *et seq.* The Court has subject matter jurisdiction under 28 U.S.C. § § 1331 and 1338(a). The Court has personal jurisdiction comporting with the United States Constitution and § 3104 of the Delaware Code. There are no issues of jurisdiction or venue. All named parties have been served with the requisite pleadings.

## **III. SUBSTANCE OF THE ACTION**

The parties' factual and legal basis is as follows:

### **A. Plaintiff**

This is an action for infringement of United States Patent No. 5,565,427 ("the '427 patent"), arising under the patent laws of the United States, 35 U.S.C. § 100 *et seq.* The '427 patent is owned by Aventis Pharma S.A. The inventions of the patent-in-suit concern novel stabilized Factor VIII solutions and novel methods of making such solutions, which are superior to prior Factor VIII solutions and methods of making such solutions. Factor VIII is a protein present in normal human blood plasma that is essential for blood coagulation (clotting). Individuals suffering from hemophilia A have a deficiency of Factor VIII in their blood plasma and rely upon infusions of Factor VIII as therapy for this disease. Plaintiff alleges that Baxter's making, using, offering for sale, selling, and importing into the United States of its ADVATE<sup>®</sup> product, which contains a stabilized solution with Factor VIII:C activity, constitutes infringement of at least one claim of the '427 patent under 35 U.S.C. § 271.

### **B. Baxter**

Baxter contends that it does not infringe any valid claim of the '427 patent, directly, contributorily, or by inducement. Baxter further contends that the '427 patent is invalid under 35 U.S.C. §§101, 102, 103 and/or 112, and is unenforceable as a result of Aventis' and/or its agents'



failure to disclose and/or misrepresentation to the U.S. Patent and Trademark Office information that was material to the patentability of the invention during the prosecution and reexaminations of the '427 patent.

#### **IV. IDENTIFICATION OF ISSUES**

There are a number of factual and legal issues in dispute, which are as follows:

##### **A. Plaintiff**

Plaintiff's factual and legal issues currently in dispute comprise at least the following:

- (1) whether Baxter's making, using, offering for sale, selling and importing into the United States of its ADVATE<sup>®</sup> product, which contains a stabilized solution with Factor VIII:C activity, constitutes infringement of at least one claim of the '427 patent under 35 U.S.C. § 271;
- (2) whether Baxter's acts of infringement have damaged Plaintiff in an amount not yet determined and will continue to damage Plaintiff in the future; and
- (3) whether Baxter's acts of infringement constitute willful infringement, entitling Plaintiff to treble damages and attorneys' fees.

##### **B. Baxter**

Baxter's factual and legal issues in dispute comprise at least the following:

- (1) The meaning and scope of the claims of the '427 patent;<sup>1</sup>
- (2) Whether Baxter's manufacture, importation, use, offer for sale, or sale of ADVATE<sup>®</sup> infringes the '427 patent;<sup>2</sup>
- (3) Whether the '427 patent is valid;
- (4) Whether the '427 patent is enforceable;
- (5) Whether Aventis is entitled to damages; and
- (6) Whether intervening rights limit or preclude Aventis' recovery of damages.

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<sup>1</sup> Baxter believes claim construction by the Court will be required. Baxter reserves its right to challenge any claim construction proffered by Aventis.

<sup>2</sup> Aventis has not yet identified which claims of the '427 patent Baxter allegedly infringes.



## **V. NARROWING OF ISSUES**

### **A. Plaintiff**

Plaintiff will seek the Court's permission to file a motion for summary judgment that Baxter's ADVATE<sup>®</sup> product infringes at least one claim of the '427 patent. The motion will show that there is no genuine issue of material fact that Baxter's<sup>®</sup> ADVATE product contains the components fully described in its product label and the FDA's Summary of Basis for Approval, and further, that these components literally infringe the claims of the patent-in-suit.

### **B. Baxter**

The Court's construction of disputed claim terms will be necessary to identify and evaluate opportunities for narrowing the issues for trial. Baxter does not agree that summary judgment motions should be filed before the close of discovery or before the Court has issued a claim construction ruling. Rather, consistent with this Court's practice in patent cases, Baxter anticipates that, after the close of expert discovery and after the Court has issued a claim construction ruling, Baxter will seek leave from the Court to file a motion for summary judgment of invalidity based on several prior art references. The motion will show that every one of Claims 2-23 of the '427 patent is either anticipated by or rendered obvious in view of the prior art. Baxter may also seek leave from the Court to file a motion for summary judgment of invalidity under 35 U.S.C. § 112, unenforceability, and/or non-infringement.

## **VI. RELIEF**

### **A. Plaintiff**

Plaintiff currently seeks the following relief at a minimum:

- (1) a declaration that, under 35 U.S.C. § 271 *et seq.*, Baxter's making, using, offering for sale, selling and importing into the United States of its ADVATE<sup>®</sup> product constitutes infringement of at least one claim of the '427 patent;
- (2) an award of damages adequate to compensate it for the aforesaid infringement, together with prejudgment interest thereon;



- (3) a declaration that Baxter's infringement has been willful and an award of treble damages under 35 U.S.C. § 284 because of Baxter's willful infringement;
- (4) a declaration that this is an exceptional case and an award of Plaintiff's attorneys fees under 35 U.S.C. § 285;
- (5) an award to Plaintiff of its costs and expenses in this action; and
- (6) an award of any further relief as this Court deems just and proper.

**B. Baxter**

Baxter seeks a judgment that no valid claims of the '427 patent are infringed by Baxter, that the '427 patent is invalid and/or unenforceable, that Baxter is not liable for damages and/or damages are limited by the doctrine of intervening rights. Baxter also seeks an award of its costs, expenses and reasonable attorneys' fees under 35 U.S.C. §285, and an award of any further relief as this Court deems just and proper.

**VII. AMENDMENT OF PLEADINGS**

The parties propose a September 14, 2007 deadline for amendment of pleadings.

**VIII. JOINDER OF PARTIES**

At present, the parties are not aware of any additional parties who should be joined in this action. The parties propose a September 14, 2007 deadline for joining additional parties.

**IX. DISCOVERY**

**A. Issues**

**1. Plaintiff**

Plaintiff requires, at minimum, the following discovery to prepare for trial: (1) written discovery to and responses and documents from Baxter; (2) fact deposition of Baxter and key employees of Baxter relating to Baxter's infringement as well as Baxter's contentions in this case; (3) expert depositions and discovery; and (4) discovery relating to damages and willful infringement. Plaintiff will have one or more expert witness.



## 2. Baxter

Baxter requires, at a minimum, the following discovery to prepare for trial: (1) written discovery responses and documents from Aventis and its predecessors-in-interest of the '427 patent; (2) fact depositions of Aventis and its predecessors-in-interest of the '427 patent, key employees of Aventis and its predecessors-in-interest of the '427 patent, and third-parties relating to invalidity and unenforceability issues; (3) depositions of Aventis' patent attorneys and/or agents relating to the validity and unenforceability issues; and (4) expert depositions. Baxter expects to have at least one technical expert witness, and a damages expert witness if necessary.

### B. Discovery Schedule

Plaintiff and Baxter propose the following schedules:

Event	Aventis Proposal	Baxter Proposal
Rule 16 Scheduling Conference	June 27, 2007	June 27, 2007
Parties exchange Initial Disclosures	July 5, 2007	July 5, 2007
Deadline to Move to Join Parties/Amend Pleadings	September 14, 2007	September 14, 2007
(If Permission Granted) Plaintiff's Motion for Summary Judgment of Infringement	October 12, 2007	N/A
Close of Fact Discovery	March 14, 2008	March 14, 2008



<b>Event</b>	<b>Aventis Proposal</b>	<b>Baxter Proposal</b>
Parties exchange claims terms to be construed and proposed constructions		March 17, 2008
Parties meet-and-confer to identify claims and terms in dispute for <u>Markman</u> hearing and briefing	May 7, 2008 <sup>3</sup> (if necessary)	March 24, 2008
Submission of Joint Claim Construction Chart		March 31, 2008
Parties simultaneously file opening <u>Markman</u> briefs	May 21, 2008 (if necessary)	April 14, 2008
Parties simultaneously file responsive <u>Markman</u> briefs	June 4, 2008 (if necessary)	May 5, 2008
<u>Markman</u> hearing	TBD (if necessary and subject to the Court's calendar)	TBD (subject to the Court's calendar)
Expert Reports on Which Party Bears Burden of Proof	April 14, 2008	One month after <u>Markman</u> Ruling
Rebuttal Expert Reports	May 14, 2008	Three weeks after service of Opening Expert Reports
Letter briefs seeking leave to file motion(s) for summary judgment	May 26, 2008	September 15, 2008
Expert Depositions to be Completed	June 16, 2008	One month after service of Rebuttal Expert Reports
Dispositive motions	June 30, 2008	November 3, 2008
Motions <i>in limine</i>	Opening: August 4, 2008 Responsive: August 18, 2008 Reply: August 25, 2008	Opening: December 15, 2008 Responsive: December 29, 2008 Reply: January 5, 2009
Plaintiff's Proposed Joint Pretrial Order	August 11, 2008	December 15, 2008

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<sup>3</sup> Plaintiff does not believe that a Markman hearing is necessary in this action. In the event the Court wishes to conduct a Markman hearing, however, Plaintiff proposes that the briefing and hearing follow Plaintiff's proposed schedule, specified above.



<b>Event</b>	<b>Aventis Proposal</b>	<b>Baxter Proposal</b>
Submission of Joint Pre-Trial Order	August 25, 2008	January 5, 2009
Final Pre-Trial Conference	September 2008 (subject to the Court's calendar)	January 2009 (subject to the Court's calendar)
Trial	October 2008 (subject to the Court's calendar)	February 2009 (subject to the Court's calendar)

### **C. Limitations on Discovery**

The parties agree that discovery should be conducted in accordance with the parameters set forth in the Federal Rules of Civil Procedure, the Local Rules of this Court, and the individual rules of the Honorable Gregory M. Sleet, subject to modification by agreement of the parties or by Court order, as necessary under the circumstances.

The parties have agreed to make all witnesses available for deposition in the United States.

The parties have agreed to limit the number of interrogatories to 75 per side. The parties do not believe that any limitations are required at this time for document requests or admission requests, as the parties have agreed to be reasonable and cooperative with respect to the number and timing of such requests propounded.

The parties have agreed that each side is limited to 15 fact depositions (including third parties), of which three may be up to 14 hours long. While the remainder of the depositions should adhere to the seven hour length set forth in the Federal Rules of Civil Procedure, the parties have agreed to work cooperatively on a case-by-case basis regarding the length of depositions as necessary.

### **D. Service**

Delaware counsel will serve by hand on the opposing Delaware counsel one copy of each



pleading, motion, discovery request and the like, and will provide an additional copy to the opposing lead counsel by Federal Express or comparable overnight delivery service or e-mail. In the case of discovery requests, each side also will e-mail an electronic, native format copy of the discovery requests to the other side within three business days after service of the discovery requests.

**E. Protective Order**

The parties anticipate the need for entry of a protective order to protect the confidentiality of sensitive business information that may be exchanged during discovery, and are in the process of finalizing a protective order for this case. The parties anticipate submitting a proposed stipulated order to the Court for its consideration.

**X. ESTIMATED TRIAL LENGTH**

The parties believe at this time that they will require at least seven six-hour trial days to resolve the issues presently pled. The parties will cooperate in an attempt to reduce the length of trial through the use of stipulations and other means for expediting the presentation of evidence.

**XI. JURY TRIAL**

Neither party has previously demanded a jury trial. Baxter requested a jury trial during the Rule 26(f) meeting, but Plaintiff did not consent.

**XII. SETTLEMENT**

The parties are presently pursuing settlement discussions.

**XIII. STATEMENT BY COUNSEL**

The parties have conferred about each of the above matters and this report sets forth their agreements.



ASHBY & GEDDES

By: /s/ Steven J. Balick  
\_\_\_\_\_  
Steven J. Balick (#2114)  
John G. Day (#2403)  
500 Delaware Avenue, 8<sup>th</sup> Fl.  
P. O. Box 1150  
(302) 654-1888  
Wilmington, DE 19899  
[sbalick@ashby-geddes.com](mailto:sbalick@ashby-geddes.com)  
[jday@ashby-geddes.com](mailto:jday@ashby-geddes.com)

*Attorneys for Plaintiff*  
*Aventis Pharma S.A.*

*Of Counsel:*

FINNEGAN HENDERSON FARABOW  
GARRETT & DUNNER LLP  
James B. Monroe  
Paul W. Browning  
Timothy B. Donaldson  
Kakoli Caprihan  
901 New York Ave., NW  
Washington, DC 20001  
Telephone: (202) 408-4000

Dated: June 21, 2007

POTTER ANDERSON & CORROON LLP

By: /s/ Philip A. Rovner  
\_\_\_\_\_  
Philip A. Rovner (#3215)  
Hercules Plaza  
P.O. Box 951  
Wilmington, DE 19899-0951  
(302) 984-6000  
[provner@potteranderson.com](mailto:provner@potteranderson.com)

*Attorneys for Defendant*  
*Baxter Healthcare Corporation*

*Of Counsel:*

TOWNSEND AND TOWNSEND AND  
CREW LLP  
James G. Gilliland Jr.  
Susan M. Spaeth  
Annie M. Rogaski  
Matthew R. Hulse  
Julie J. Han  
Eric A. Mercer  
379 Lytton Ave.  
Palo Alto, CA 94301  
Telephone: (650) 326-2400